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PATENT
Atty. Docket No. SSI-011
(7703/14)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Wilkie *et al.*	CONFIRMATION NO.:	2615
SERIAL NUMBER:	09/747,293	GROUP ART UNIT:	1654
FILING DATE:	12/22/2000	EXAMINER:	R. Teller
TITLE:	Methods and Compositions for Sealing Tissue Leaks		

Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. 1.131

Sir:

We James Wilkie and Eugene Pashkovski hereby declare as follows:

1. We, together with James Rolke, Luis Burzio, Shekharam Tammishetti, and Sanyog Manohar Pendharkar, are co-inventors of the subject matter described and claimed in the above-identified patent application.

2. We make this declaration to swear behind the effective date of U.S. Patent No. 6,162,241, entitled "Hemostatic Tissue Sealants" and filed August 5, 1998, which claims priority to U.S. Provisional Patent Application No. 60/054,846, filed August 6, 1997.

3. We, James Wilkie and Eugene Pashkovski, declare that, prior to August 6, 1997, we had conceived and actually reduced to practice in the United States a platelet-free tissue sealant or adhesive comprising a protein solution and a surfactant preparation. In support of our statements, we submit herewith copies of original notebook records which together demonstrate an actual reduction to practice prior to August 6, 1997.

4. We attach as Exhibit A copies of laboratory notebook pages recording the procedure and results of tissue adhesive formulation experiments. In the experiments, two tissue adhesive preparations, identified as emulsions E-1 and E-2, were prepared. As described on the first page of Exhibit A, each preparation contained calf collagen gel, water, hexane, and polyethylene oxide-dimethylsiloxane. Polyethylene oxide-dimethylsiloxane is a non-ionic surfactant having the chemical structure indicated on the third page of Exhibit A. The adhesive energy or work of adhesion between each preparation and ePTFE was determined by a lap shear test, as illustrated on the third page of Exhibit A. The results of these experiments, recorded on the fourth page of Exhibit A, showed that emulsions containing collagen and a non-ionic surfactant improved the adhesion between collagen and ePTFE. In addition, the fifth page of Exhibit A describes the procedures for further tissue adhesive formulation experiments. The proposed tissue sealants include non-ionic surfactants such as poly(propylene oxide)-*block*-poly(ethylene oxide)-*block*-poly(propylene oxide), poly(ethylene oxide)-*block*-poly(dimethylsiloxane), and stearate-*block*-poly(ethylene oxide)-*block*-stearate.

5. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like, so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: June 27, 2003 James Wilkie

Date: _____ Eugene Pashkovski